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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,572	06/07/2001	Yading Wang	460063.93	8128

7590

02/26/2003

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EXAMINER

MCLENDON, SANZA L

ART UNIT	PAPER NUMBER
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1711

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/876,572

Applicant(s)

WANG ET AL.

Examiner

Sanza L McClendon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 47 and 48 is/are allowed.
- 6) ☐ Claim(s) 1-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Response to Amendment

1. In response to the Amendment received on December 02, 2002, the examiner has carefully considered the amendments. The examiner acknowledges the cancellation of claim 10.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 5, 7-9, 12-14 and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoffman et al (3,826,678).

Claims 1-3, 5, 7-9, 13, 17-19, 21-23, 25, 27-30, 33, 37-39, and 41-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldberg et al.

Claims 1-18, 21-39, and 41-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Ottersbach et al (6,001,894).

The text of the above actions can be found in a prior Office action.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 20 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ottersbach et al (6,001,894).

The text of the action can be found in a prior office action.

Response to Arguments

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5. The actions associated with the above rejections can be found in paper number 7, mailed September 5, 2002. In addition, the rejected claims under said rejection have changed. Claims 12-14 has been added to the 35 USC 102(b) rejection under Hoffman et al (3,826,678). Claims 4, 6, have been removed from the 35 USC 102(b) rejection under Goldberg et al, wherein claims 13, 30 and 33 have been added. Claim 19 has been removed from the 35 USC 102(e) rejection under Ottersbach et al (6,001,894). All claims that have been removed are deemed not to be anticipated by the reference as applied in the Office action dated September 5, 2002, subsequently all added claims are deemed to be anticipated after reconsideration of the art in view of the amendments.

6. Applicant's arguments filed December 02, 2002 have been fully considered but they are not persuasive. Applicant appears to be relying on the limitation in step (b) of the independent process claim 1, which states, "wherein, an initiator initiates the polymerization of the swelling monomer" to overcome the prior art, however it is clear from claims 11-14 that the initiator in claim 1 can in fact be the form of radiation used in addition to being an added initiating compound, such as a thermal initiator or photoinitiator.

Applicant's states that the claimed invention is not anticipated by Hoffman et al (3,826,678) because teaches methods of radiation grafting reactable compounds (polymers and copolymer) onto an inert surface and subsequently covalently attaching biologically active molecules. The examiner respectfully disagrees with applicant. Hoffman et al teaches radiation grafting of hydrogels onto inert polymeric substrate, wherein said hydrogel is formed onto the surface of said substrate by radiation grafting hydrogel-forming monomer and/or monomer mixtures (in the case of copolymer-type hydrogels) onto the surface of said substrate. The examiner refers applicant to column 5, lines 30-36, which states the radiation grafting process comprises pre-swelling the inert polymeric substrate in the grafting solution, which comprises a monomer or monomer mixture and a solvent (see columns 4, lines 11-46), removing the solution, removing air by evacuation, and irradiating the swollen polymeric substrate—see column 5, lines 30-36. In addition example 1 teaches swelling an inert polyurethane substrate in a solution of hydroxyethyl methacrylate (HEMA, a monomer) and methanol (swelling solvent) and then irradiating with gamma irradiation. Claims 12-14 have been added to the Hoffman et al rejection because it is deemed that the

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gamma radiation anticipates when the initiator is ionizing radiation, which generally speaking includes gamma radiation. In addition, Hoffman et al teaches using the oxygen in air in the presence of gamma radiation to form peroxy or hydroperoxy groups on the surface of the substrate, wherein the oxygen is deemed to be a chemical catalyst, immersing the peroxy containing substrate in the monomer solution and then heating, which anticipates when the initiator is heat.

It is noted that Applicant states Goldberg et al fails to disclose polymerization with an initiator and that the reference is unsupported by the art, however Goldberg et al teaches to be surface-modified according to the method the substrate is pre-soaked in a grafting monomer (or mixture of monomers) or in a first aqueous solution of a grafting monomer for a period of time at a temperature sufficient to facilitate diffusion of the monomer(s) into the substrate surface—see column 10, lines 59-65 and then gamma irradiated to obtain the surface modification. Per applicant's admission, see claims 11-14, the exposure to energy is considered to be an initiator suitable for initiating polymerization. Therefore, Goldberg et al is deemed claims of 1-3, 5, 7-9, 13, 17-19, 21-23, 25, 27-30, 33, 37-39, and 41-46 are anticipated by the reference as suggested in the Office action mailed September 05, 2002 because Goldberg et al teaches immersion of a substrate in a monomer solution to swell the polymer substrate with said monomer and/or monomers and then polymerizing said immersed substrate for surface modification by gamma radiation.

Applicant states that Ottersbach et al fails to anticipate the claimed invention because Ottersbach et al fails to teach the swelling monomers are absorbed by the polymer substrate. The examiner disagrees and refers applicant to column 6, lines 55-57 and column 7, line 60 to column 8, line 2, which states that the monomer must be able to initiate swelling of the polymer substrate and thus allow penetration of the initiator and, additionally, Ottersbach et al teaches in the variant A embodiment teaches the monomers and initiator that adheres to the surface can be removed prior to graft polymerization which makes it possible to obtain an extraction-resistant and homogeneous coating once polymerized. Therefore the examiner contends that Ottersbach et al inherently teaches that the swelling monomer is absorbed by the polymer substrate because, as stated above, the monomer swells the substrate to allow penetration of the initiator and once swelled said substrate can be washed to remove any monomer and initiator that has

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adhered to the surface of said substrate to provide an extraction-resistant and homogenous coating upon graft polymerization. Applicant's reference to column 1, lines 31-41, however the examiner contends column 1, lines 31-41 is general background information that provides definitions regarding the general knowledge in the art and not related to applicant's instant embodiments.

With respect to the arguments for claims 20 and 40 regarding no prima facie case of obviousness, the examiner respectfully disagrees. It is noted that Ottersbach et al teaches surface modification for hygiene products, however Ottersbach et al teaches said surface modification is useful for medical products, such as blood bags and catheters (see column 9, lines 28-29), in addition; to teaching that depending on the functional groups of the grafting monomers surfaces can be modified to be used as cell-proliferation-inhibiting surfaces—column 5, lines 7-8. It is noted that Ottersbach et al does not expressly suggest anti-coagulation as a surface modification. However combined with the teaching that said surface can be modified to be cell-proliferating/inhibiting and the products (articles) obtained by Ottersbach et al process' can be useful for medical products, such as blood bags and catheters, one of general skill in the art could have been motivated to solve the problem of blood clotting of the surface of a blood bag by modifying the surface of said blood bag with a art-recognized blood coagulate, such as heparin, in the absence of unexpected results.

Allowable Subject Matter

7. Claims 47 and 48 are allowed.

8. The following is an examiner's statement of reasons for allowance: see office action mailed September 05, 2002 (paper number 7).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sanza L McClendon whose telephone number is (703) 305-0505. The examiner can normally be reached on Monday through Friday 8:00 to 4:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (703) 308-2462. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0657.

Sanza L McClendon
Examiner
Art Unit 1711

SMc

February 20, 2003


Supervisory Patent Examiner
Technology Center